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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,374	03/12/2007	Joseph C. Rongione	15344US02	3721

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EXAMINER	
CUTLIFF, YATE KAI RENE	
ART UNIT	PAPER NUMBER
1621	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,374	RONGIONE ET AL.	
	Examiner	Art Unit	
	YATE' K. CUTLIFF	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1, 2 and 4-20 are pending.

Claims 3, 21 and 22 have been canceled

Claims 1, 2 and 4 - 20 are rejected.

Response to Amendment

2. The amendment to claims 1 and 8, submitted March 13, 2009 is acknowledged and entered.

Response to Arguments

3. Applicant's arguments, see page 5, filed March 13, 2009, with respect to claims 21 and 22 have been fully considered and are persuasive in view of the cancellation of the claims. The 35 U.S.C. 102(b) rejections of claims 21 and 22 have been withdrawn.

4. Applicant's arguments, see pages 5-7, filed March 13, 2009, with respect to the rejection(s) of claim(s) 1, 2 and 4 - 7 under 35 U.S.C. 103(a) have been fully considered and are persuasive in view of the amendment. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Ghisalberti (WO 2001/18161) and Seabo et al. (US 6,410,761).

5. Applicant's arguments filed March 13, 2009, with regard to the 35 U.S.C. 103(a) rejections of claims 8 - 20 have been fully considered but they are not persuasive for the reasons set out below.

37 CFR 1.132 Declaration

6. The Declaration under 37 CFR 1.132 filed March 13, 2009 is insufficient to overcome the rejection of claims 1, 2 and 4-20 based upon 35 U.S.C. 103(a) rejections as set forth in the last Office action because: Applicant directs Examiner to Example 1 in Applicant's Specification. It is stated in the Declaration that this example illustrates a molecular distillation process similar to the process used in Saebo et al. (US 6,410,761). It is noted that in Example 1, the temperature ranges are 120 to 125°C and with the apparatus being a low residence time distillation apparatus. However, in Example 1, one skilled in the art would presume that each distillation pass is conducted at a temperature well below the temperature 190°C used in the Saebo et al. patent. Further, in Saebo et al. the distillation is conducted in less than one minute. Applicant's Example 1 does not provide data as to the amount of time involved in the distillation process. Additonally, the Saebo et al. patent only discourages conducting the distillation process at elevated temperatures between 180 and 200°C over an extended period of time, i.e. several hours.

Applicant, even compared the results of Example 1 with the Results of Example 6 of their specification, however, no time was given in Example 6. From the discussion in both the Seabo patent and Applicant's Exhibit A, residence in conjunction with temperature has an affect on outcome of the refining process. Thus, based on the lack of information provided in Applicant's Example 1 when compared to Saebo et al. (closest prior art), it is not clear to the Examiner that the results of the process are unexpected.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghisalberti (WO 2001/18161) in view of Seabo et al. (Us 6,410,761).

11. The rejected clams cover, inter alia, a process to refine a conjugated linoleic acid-containing material comprising: distilling a first ester stream containing esters of conjugated linoleic acids using a distillation apparatus containing a fractionating column and a heater, wherein the heater is operated at a temperature in the range of 240° C to 270° C, the first ester stream comprising c9,tll and t10,c12 isomers of the esters of conjugated linoleic acids; and producing a second ester stream enriched in the c9,tll and t10,c12 isomers of the esters of conjugated linoleic acids. Dependent clams 2 and 4-7 further limit the distillation process.

12. Ghisalberti discloses a process for the preparation of conjugated linoleic acid (CLA) where the term CLA includes the ester form of conjugated linoleic acid. (see page 4, lines 13-16). In the process of Ghisalberti, in order to obtain high grade CLA the product is refined by conventional refining techniques which include stripping as vacuum distillation techniques or the like. (see page 7 lines 24-25 to page 8 lines 1-3). The process produces a product enriched in CLA isomers where c9,c11, c9,t11 and c10,c12 and t10,c12 are most abundant in the mixed CLA. (see page 8, lines 5-11).

13. The difference between Ghisalberti and Applicant's claimed process is the following; use of a fractionating column with a heater operated at temperatures of 240°C to 270°C; a multi-pass distillation operation; distillation apparatus

operating pressure between 0 and 760 mmHg and removal of unconjugated linoleic acid components.

14. With regard to the use of a fractionating column, Ghisalberti's process can use standard distillation means, which would include the use of known apparatus such as a fractionation column. Ghisalberti states that these conventional means are used to refine CLA and its derivatives. Also, it obtains an enriched product. Applicant's claim 1 obtains a product enriched in c9,t11 and t10,c12. However, from the teachings of Ghisalberti, it is known that isomers of CLA remain after distillation. As such, one skilled in the art would expect that since Applicant is merely using conventional distillation that even though they are enriching the amount of c9,t11 and t10,c12, just like the teachings in Ghisalberti, other isomers will remain. Additionally, in the view of the fact that the claims do not limit the isomers in the ester product to the enriched isomers.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a known technique, conventional distillation as suggested by Ghisalberti to refine CLA with one such conventional distillation apparatus to include a fractionating column, since Ghisalberti states that like distillation techniques can be used, and achieve enriched CLA esters with a reasonable expectation of success.

Thus, the claims would have been obvious because the technique for refining CLA to provide an enriched CLA using distillation was part of the ordinary skill in the art, in view of the teaching of Ghisalberti. In applying known technique to a known device (method, or product) ready for improvement to yield

predictable results, the claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. The Supreme Court in *KSR* noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then the resulting invention would not have been obvious because one of ordinary skill could not have been expected to achieve it.

15. With regard to the distillation operating temperatures of 240°C to 270°C, it would be within the purview of one skilled in the art to adjust the operating temperature in the distillation process to obtain the desired purity in view of the fact that Ghisalberti states that distillation can be used to refine the CLA. Additionally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)).

16. With regard to the use of multiple passes in the distillation step this is within the purview of one skilled in the art desiring further refine the CLA using the know distillation processes in use at the time of applicant's claimed process. Thus, the use of multi-pass distillation is drawn to routine tweaking, since its use is dependent upon the desire of the operator as to the amount of impurities or by-products they want to remove from the crude CLA, and the skilled artisan would be motivated to do so in order to improve the purity of the product.

17. With regard to the operating pressure between 0 and 760 mmHg the Examiner turned to the teachings of Seabo et al. In the process of Saebo et al. after the conjugation reaction the resulting CLA containing composition may be further purified (refined). In the purification process, the resulting CLA is distilled at 190°C in a molecular distillation plant at a vacuum of 10^{-1} to 10^{-2} milliard (0.075 to 0.008 mmHg). Thus, this limitation is deemed to be obvious absent a showing of unexpected results.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. *(In reOpprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

18. With regard to the removal of unconjugated linoleic acid components, Ghisalberti states that further refining can be done using known distillation processes to refine a final product as set out in Ghisalberti's Table 1. Seabo et al. discloses a distillation process that can further refine a final product of

Ghisalberti's. Specifically, Seabo's process contemplates the removal of any undesirable by-products.

For the reasons set forth above in paragraph 18, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare and further refine the CLA of Ghisalberti as suggested by Seabo et al. and partially removing unconjugated linoleic to produce the refined CLA ester.

Therefore, all the claimed elements were known in the prior arts of Ghisalberti and Seabo et al., and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. KSR International Co. v. Teleflex Inc., 550 U.S. ___, 82 USPQ2d 1385 (U.S. 2007).

19. Claims 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saebo et al. (US 6,410,761) in view of Baltes et al. (US 3,162,658) and further in view of Sachtler (US 5,326,925), for the reasons set out in the Office Action mailed October 15, 2008; and as set out below.

20. Applicant amended claim 8 to include the limitation of "a distillation apparatus comprising a fractionating column". Further, Applicant respectfully asserts that at the time of the claimed process, the state of the art taught that distillation with a high temperature apparatus, such as rectification column (fractionation column) should be avoided and that molecular distillation at low temperature and low distillation time should be used. Specifically, that batch

distillation that involves high temperature and long residence time should be avoided, as suggested in Seabo et al.

21. As Examiner reads Seabo et al, it only teaches that elevated temperatures between 180 to 200°C for long periods should be avoided. However, there are no time indications provided in Applicant's claimed process, specification or 1.132 Declaration. Further, Applicant's claimed process enriches CLA with c9,t11 and t10,c12 by distillation, which is the same intended purpose of distillation process of Seabo et al. Furthermore, Seabo does not teach or suggest that distillation temperatures above 200°C for shorter or longer periods of time are to be avoided. More importantly, Applicant's Exhibit A points to the fact that it was known in the art at the time of the claimed process that varying the variable of temperature would allow one skilled in the art to obtain new isomers of CLA. Thus, one skilled in the art with a desire to refine CLA via isomer enrichment would have been motivated to vary the temperature parameters to achieve the desired isomer purity.

The primary reference of Seabo et al. patent does not teach away from Applicant's claimed process. Exhibit A, Seabo's chapter 5, actually provides motivation for one skilled in the art to vary the parameters to achieve the desired isomers. Therefore, the process of claims 8-20 are deemed obvious prima facie in view of the prior art references.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number

is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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